REMARKS

I. STATUS OF THE APPLICATION

Claims 22-41 and 59-66 were pending in the Application as of the date of the Office Action. In the Office Action, the Examiner:

(a) objected to claim 66 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement;

(b) rejected claims 22-24, 29, 30, 35, 36, and 59-65 under 35 U.S.C. § 103(a) as allegedly being unpatentable over European Patent Publication No. EP1025805A1 to Krivitski (the "'805 Krivitski") in view of U.S. Patent No. 5,453,576 to Krivitski (the "'576 Krivitski");

(c) rejected claim 25 under 35 U.S.C. § 103(a) as allegedly being unpatentable over '805 Krivitski in view of '576 Krivitski and in further view of U.S. Patent No. 5,665,103 to Lafontaine et al. ("Lafontaine");

(d) rejected claims 26-28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over '805 Krivitski in view of '576 Krivitski and in further view of U.S. Patent No. U.S. Publ. No. 2004/0254495 A1 to Mabary et al. ("Mabary");

(e) rejected claims 37-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over '805 Krivitski in view of '576 Krivitski and in further view of U.S. Publ. No. 2002/0049488 A1 to Boneau ("Boneau");

(f) rejected claims 40-41 under 35 U.S.C. § 103(a) as allegedly being unpatentable over '805 Krivitski in view of '576 Krivitski and in further view of U.S. Patent No. 6,471,656 to Shalman et al. ("Shalman"); and

(g) allowed claims 31-34.

In response to the Office Action, Applicants amend claim 22 and address each of these rejections and objections. Claims 31-34 have been allowed by the Examiner and remain in the present Application. Reconsideration of the rejections and objections, as well as allowance of the pending claims, are respectfully requested in light of the present amendments and comments below.

II. ACKNOWLEDGEMENT OF TELECONFERENCE WITH EXAMINER SZMAL

The undersigned would like to thank Examiner Szmal for his time on June 2, 2008, to discuss the claims of the Application along with one of the inventors of the Application, Dr. Ghassan S. Kassab.

During the teleconference, those in attendance discussed the incorporation of the term "instantaneous" within the preamble and the last claim element of claim 22 to further clarify the type of "cross-sectional area" claimed therein. This particular claim amendment was considered by Applicants in view of item 11 of the Office Action where Examiner Szmal noted that although the Applicants discussed the measurement of instantaneous cross-sectional area within Applicants' then most-recent response to office action, the limitation "instantaneous" was not actually recited in the rejected claims. In response, Applicants have amended claim 22 to incorporate the term "instantaneous" to further clarify "cross-sectional area" within the last element of claim 22. In addition, Applicants have also incorporated the same term into the preamble at the suggestion of Examiner Szmal during the teleconference.

Furthermore, Examiner Szmal, Dr. Kassab, and the undersigned also generally discussed claim 66 and the Applicants' desire to demonstrate support within the specification of the

Application for said claim. Examiner Szmal encouraged Applicants to provide such information with Applicants' forthcoming response, and Applicants respectfully submit that such support is provided below in Section IV.

III. NO NEW MATTER IS INTRODUCED BY WAY OF AMENDMENT

Applicants respectfully submit that no new matter has been added by amending claim 22. Specifically, the amendment to claim 22 incorporates the term "instantaneous" within the preamble and the last claim element of claim 22 to further clarify the type of "cross-sectional area" claimed therein. Applicants respectfully submit that this amendment is supported by the originally filed Application and does not add new matter. Accordingly, Applicants respectfully request that the amendment be entered so that the Application may proceed to allowance.

IV. THE OBJECTIONS TO CLAIM 66 ARE OVERCOME AND SHOULD BE WITHDRAWN

In the Office Action, the Examiner rejected claim 66 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. As noted by the Examiner, "[t]he newly amended claim discloses a method for measuring a cross sectional area of a treatment site by injecting a first and second solution at the site and calculating the cross sectional area based on the measured conductances of the solutions, and inflating the balloon and measuring the cross sectional area based on the conductance inside the balloon," and that "[t]he current specification is silent with regards to measuring the cross sectional area using the two methods at the same time." Office Action, page 2.

Claim 66, in its present form, claims "a method for measuring the cross-sectional area of a treatment site," containing a number of the same elements as found in allowable claim 31, including the step of "calculating the cross-sectional area of the treatment site based on the first and second conductance values and the conductivities of the first and second solutions." Applicants respectfully submit that support for this particular step and the preceding steps can be found, for example, at paragraph 0029 of the Application, which states:

> In one approach, a method of measuring the cross-sectional area of a targeted treatment site comprises: introducing an impedance catheter into a treatment site; providing constant electrical current to the treatment site; injecting a first solution of first compound; measuring a first conductance value at the treatment site; injecting a second solution of a second compound; measuring a second conductance value at the treatment site; calculating the cross-sectional area of the treatment site based on the first and second conductance values and the conductivities of the first and second compounds.

The remainder of claim 66 includes the elements of selecting an appropriately-sized stent and implanting the stent into the treatment site. Applicants respectfully submit that support for these particular steps can be found, for example, at paragraph 0048 of the Application, which states (in relevant part):

> This invention makes accurate measures of the luminal cross-sectional area of organ stenosis within acceptable limits to enable accurate and scientific stent sizing and placement in order to improve clinical outcomes by avoiding under or over deployment and under or over sizing of a stent which can cause acute closure or in-stent re-stenosis. In one embodiment, an angioplasty or stent balloon includes impedance electrodes supported by the catheter in front of the balloon. These electrodes enable the immediate measurement of the cross-sectional area of the vessel during the balloon advancement. This provides a direct measurement of non-stenosed area and allows the selection of the appropriate stent size.

In addition, claim 66 includes the elements of inflating with a fluid a balloon attached to the catheter, providing electrical current into the fluid filling the balloon at various degrees of balloon distension, measuring the conductance of the fluid inside the balloon, and calculating the cross-sectional area of the balloon lumen. Applicants respectfully submit that support for these steps can be found, for example, at paragraph 0059 of the Application, which states:

> In one embodiment, shown in FIG. 1B, the catheter 39 includes another set of excitation electrodes 40, 41 and detection electrodes 42, 43 located inside the angioplastic or stenting balloon 30 for accurate determination of the balloon cross-sectional area during angioplasty or stent deployment. These electrodes are in addition to electrodes 25, 26, 27 and 28.

Additional support may be found at paragraph 0051, which states (in relevant part):

> In another embodiment, additional impedance electrodes may be incorporated in the center of the balloon on the catheter in order to deploy the stent to the desired cross-sectional area. The procedures described herein substantially improve the accuracy of stenting and improve the cost and outcome as well.

Support for the fluid within the balloon can be found, for example, at paragraph 0065, which states (in relevant part):

> The suction/infusion port 35, 36, 37 can be placed as shown with the balloon or elsewhere both proximal or distal to the balloon on the catheter. The fluid inside the balloon can be any biologically compatible conducting fluid. The fluid to inject through the infusion port or ports can be any biologically compatible fluid but the conductivity of the fluid is selected to be different from that of blood (e.g., NaCl).

Applicants respectfully submit that as there is support within the specification of the Application for each of the aforementioned elements of claim 66, the Examiner's rejection to claim 66 under 35 U.S.C. § 112, first paragraph, is overcome, and as such, Applicants

respectfully request that the rejection to claim 66 be withdrawn to allow claim 66 to proceed to allowance.

V. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A) ARE MOOT AND SHOULD BE WITHDRAWN

In the Office Action, the Examiner rejected claims 22-30, 35-41, and 59-65 under 35 U.S.C. § 103(a) as allegedly being unpatentable over several prior art references. Applicants respectfully submit that within these rejected claims, claim 22 is the only independent claim, and claims 23-30, 35-41, and 59-65 either directly or ultimately depend from independent claim 22. In the Office Action, the Examiner only presented one rejection pertaining to claim 22, namely the rejection of claims 22-24, 29, 30, 35, 36, and 59-65 under 35 U.S.C. § 103(a) as allegedly being unpatentable over '805 Krivitski in view of '576 Krivitski.

In brief response, Applicants respectfully submit that neither '805 Krivitski nor '576 Krivitski, alone or in view of one another, disclose each and every element of amended claim 22 of the present Application. Specifically, Applicants' respectfully submit that neither Krivitski reference, either alone or in combination with one another, teaches, discloses, or suggests the final element of "calculating the ***instantaneous*** cross-sectional area of the treatment site based on the first and second conductance values and the conductivities of the first and second solutions" (emphasis added) of Applicants' currently amended claim 22. As such, Applicants respectfully submit that claim 22, and all claims dependent therefrom, are allowable.

The '805 Krivitski discloses performing a single-injection method to determine a blood flow (or cross-sectional area), performing a second single-injection method to determine a second blood flow, then merely comparing the two blood flows to determine whether there has

been any change in blood flow over the period of time between the two injections. (*See* '805 Krivitski, ¶¶ 0059-62; *see also id.* ¶¶ 0012-13.) Not only does this method use two injections only to determine a change in flow over time, each of its single-injection measurements provides only an average blood flow (and therefore an average cross-sectional area) calculated over time, as evidenced by the '805 Krivitski method's reliance on integrals and areas under the curve. (*See, e.g.*, '805 Krivitski, ¶¶ 0046, 0049, 0052; fig. 7.)

By contrast, Applicants' claimed method calculates an ***instantaneous cross-sectional area***, rather than an average cross-sectional area or the change in cross-sectional area over time, based on the first and second conductance values and the conductivities of the first and second solutions. (*See* Application, claim 22; *id.*, pg. 13, ll. 14-16 ("The values of CSA(t) and $G_p(t)$ can be determined at end-diastole or end-systole (i.e., the minimum and maximum values) or the mean thereof."); *see also id.*, pg. 12, l. 26 – pg. 13, l. 21.) The average cross-sectional area can be determined from the instantaneous cross-sectional area, but the instantaneous cross-sectional area cannot be determined from an average cross-sectional area.

The ability to determine an instantaneous cross-sectional area is important because it permits physicians to obtain an accurate, immediate measurement of the cross-sectional area of a blood vessel during a medical procedure, such as the placement of a stent. (*See* Application, pg. 5, ll. 22-31; *id.*, pg. 7, l. 22 – pg. 8, l. 9.) Furthermore, analysis of instantaneous cross-sectional area values – but not of average cross-sectional area values – provides the pulsatility of the vessel, which gives an indication of the compliance or stiffness of the vessel as a measure of the extent of disease. (*See id.*, pg. 17, ll. 12-19 ("When the CSA, pressure, wall thickness, and flow data are determined according to the embodiments outlined above, it is possible to compute the

compliance (e.g., ΔCSA/ΔP), tension . . . , stress . . . , strain . . . , and wall shear stress . . . . These quantities can be used in assessing the mechanical characteristics of the system in health and disease.").)

Therefore, Applicants respectfully submit that neither Krivitski reference, either alone or in view of one another, teaches, suggests, or discloses the final element of "calculating the instantaneous cross-sectional area of the treatment site based on the first and second conductance values and the conductivities of the first and second solutions" of Applicants' claim 22. As such, Applicants respectfully submit that claim 22, as presently amended, is patentable over the two Krivitski references, and Applicants respectfully request that claim 22, and all claims dependent therefrom, are allowable. Consequently, Applicants respectfully request that the rejection to claim 22 under 35 U.S.C. § 103(a) be withdrawn, allowing claims 22-30, 35-41, and 59-65 to proceed to allowance.

VI. ADVISORY ACTION REQUESTED

Applicants respectfully submit that this Response is being effectively filed within two months of the mailing of the final Office Action. Accordingly, Applicants respectfully request an Advisory Action from the Examiner stating that the present Application is in a condition for allowance. Should the Examiner recognize any matters of form that the Examiner can change without authorization from Applicants (under MPEP § 1302.04), Applicants respectfully request that such changes be made prior to the issuance of the Advisory Action acknowledging that the Application is in a condition for allowance.

VII. INTERVIEW REQUEST

In the interest of advancing prosecution of this Application in a most efficient manner, if the Examiner determines that there are any further objections or rejections that would prevent claims 22-41 and 59-66 of Application from proceeding to allowance, Applicants respectfully request that the Examiner contact the undersigned to arrange an interview with the undersigned to discuss such objections or rejections prior to the issuance of an Advisory Action.

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that Applicants have made a patentable contribution to the art and that this response places the Application in condition for allowance. Accordingly, favorable reconsideration and allowance of claims 22-41 and 59-66 of this Application is respectfully requested. In the event Applicants have inadvertently overlooked the need for a payment of a fee or extension of time, Applicants conditionally petition therefor, and authorize any fee deficiency to be charged to deposit account 09-0007. When doing so, please reference the above-listed docket number.

Respectfully submitted,

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